

YEZTUGO[®] (lenacapavir)

Does body weight change with use of YEZTUGO?

This information is provided in response to your question. It is not treatment advice on how to use **YEZTUGO**. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **YEZTUGO Patient Information** for more details, including approved use(s) and important warnings: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_patient_pi.pdf

The short answer

- **Weight loss was seen in studies of YEZTUGO.**¹⁻³
- In a study called **PURPOSE 1** in cis women who got YEZTUGO¹:
 - **1 woman** had a **decrease in weight that was severe**.
 - **8 women** had **abnormal weight loss that was severe**. It was life-threatening in 1 of these women.
- In a study called **PURPOSE 2** in cis men and gender diverse people who got YEZTUGO^{3,4}:
 - **2 people** had a **decrease in weight that was severe**.³
- Tell your healthcare provider if you have any changes in weight or other possible side effects.

What is the most important information I should know about YEZTUGO?⁵

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

YEZTUGO has an important warning for: **Chance of developing resistance to YEZTUGO if you have or get HIV-1 while receiving YEZTUGO.** Resistance means that over time your HIV-1 may become harder to treat.

You must be HIV-1 negative to start YEZTUGO. You must get tested to make sure that you do not already have HIV-1. Do not receive YEZTUGO unless you are confirmed to be HIV-1 negative.

Some HIV tests can miss HIV-1 in a person who has just gotten it. Tell your healthcare provider if you had a flu-like illness within the last month before starting YEZTUGO or at any time while receiving it. If you have flu-like symptoms, you could have recently gotten HIV-1.



The symptoms of new HIV-1 include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in your neck or groin.

You must stay HIV-1 negative to keep receiving YEZTUGO. Know your HIV-1 status and the HIV-1 status of your partners. Get tested for HIV-1 with each YEZTUGO injection or when your healthcare provider tells you. You should not miss any HIV-1 tests. If you get HIV-1 and continue receiving YEZTUGO because you do not know you have HIV-1, the HIV-1 may become harder to treat.

If you think you were exposed to HIV-1, tell your healthcare provider right away. They may want to do more tests to be sure you do not have HIV-1.

If you get HIV-1, you will need to immediately take other medicines to treat HIV-1. YEZTUGO is not approved for treating HIV-1. If you have HIV-1 and receive only YEZTUGO, over time your HIV-1 may become harder to treat.

Who is YEZTUGO for?⁵

YEZTUGO is a prescription medicine used for HIV-1 PrEP to reduce the chance of getting HIV-1 from sex in adults and teenagers who weigh at least 77 pounds (35 kg). HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).



You must be HIV-negative before you start YEZTUGO. You must get tested to make sure that you do not already have HIV-1.



Talk to a healthcare provider about your chance of getting HIV and if YEZTUGO is right for you. If you do not have a healthcare provider, the PrEP Locator website (<https://www.PrEPLocator.org>) can help you find a healthcare provider in your area who has experience prescribing PrEP medications.

Were changes in body weight seen in the research studies of YEZTUGO?

The **two main studies** of YEZTUGO are called PURPOSE 1 and PURPOSE 2.⁵ In **PURPOSE 1**, YEZTUGO was studied in **2138 cis women** without HIV.^{1,2} In **PURPOSE 2**, YEZTUGO was studied in **2183 cis men and gender diverse people** without HIV.⁴

In **PURPOSE 1**:

- **1 woman** who got YEZTUGO had a **decrease in weight that was severe**.
- **8 women** who got YEZTUGO had **abnormal weight loss that was severe**. It was **life-threatening** in **1** of these women.



In **PURPOSE 2**:

- **2 people** who got YEZTUGO had **abnormal weight loss that was severe**.

What should I do if I think I am having a side effect?⁵

If you are having a side effect, please talk to your healthcare provider. **You are encouraged to report side effects of prescription drugs to the FDA.**

Visit <https://www.fda.gov/safety/medwatch> or call 1-800-FDA-1088.

Tell your healthcare provider if you had a flu-like illness within the last month before starting YEZTUGO or at any time while receiving it. If you have flu-like symptoms, you could have recently gotten HIV-1.



The symptoms of new HIV-1 include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in your neck or groin.

Glossary

AIDS (acquired immunodeficiency syndrome): most advanced stage of HIV.

Cisgender man (or cis man): a man who was considered and assigned as male at birth.

Cisgender woman (or cis woman): a woman who was considered and assigned as female at birth.

HIV (Human Immunodeficiency Virus): HIV is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

Pre-exposure prophylaxis (PrEP): means routinely taking prescription medicine before you're exposed to HIV to help reduce your chances of getting it.

Side effect: secondary unwanted effect that occurs due to drug therapy.

References

1. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women [Supplementary Appendix]. *N Engl J Med*. 2024;1-69.
2. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med*. 2024;391(13):1179-1192.
3. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons [Supplementary Appendix]. *N Engl J Med*. 2024.
4. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med*. 2024.
5. Enclosed, Gilead Sciences Inc. YEZTUGO® (lenacapavir) tablets, for oral use. YEZTUGO® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.

More information about YEZTUGO

If you would like more detailed information about YEZTUGO, please visit:
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.pdf.

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for YEZTUGO. It will tell you about the uses, warnings, and other important safety information about YEZTUGO.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for YEZTUGO. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of YEZTUGO in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:
☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.patient.askgileadmedical.com/

Reporting side effects

Please report all adverse events to:
Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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